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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,304	09/05/2003	Andrea M. McPhillips	02972938	8208

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/656,304

**Applicant(s)**

MCPHILLIPS ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/3/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to claims filed on 9/5/03. Claims 1-10 are examined on the merits herein. It is noted that this is a continuation-in-part of Patent # 6,747,058 which claims priority to Provisional Application # 60/150,023.

#### ***Claim Objections***

##### **Drawings**

Multiple discrepancies are noted between the description of the drawings in the specification and the label of the drawings disclosed.

There appears to be no heading/description on Figures 21-22.

##### **Specification**

The recitation 10 nM is objected to as a typographical error. This does not correlate with the recitation of 10  $\mu$ M in the parent application (09/639289).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second, paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The recitation "1 up to about 10 yM" in claim 1 renders these claims indefinite. The value "yM" is not clearly defined in the specification.

2) The recitation "relative volumetric ratio amounts sufficient" in claim 1 is not clearly defined in the claims or the specification. One of ordinary skill in the art would not be able to reasonably interpret the relative term.

3) Claims 2-4 are vague and indefinite because it is not clear as to what the mL is referring to. Does it refer to the mL of the solvent or something else?

4) Claim 4 lacks antecedent basis, as it does not fall in the numerical range presented in the claim it depends from. Claim 3 comprises the numerical range of 0.1 to 25 mg/mL and Claim 4 comprises 50 mg/mL.

5) Claim 10 is indefinite for the recitation "suitable liner". The term "suitable liner" is not defined by the claims or the specification. One of ordinary skill in the art could not interpret what a suitable liner may consist of.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573).

Touitou teaches a medical composition comprising ethanol (49%), water (29.4%), and propylene glycol (19.6%) in combination with tetrahydrocannabinol (THC; 7  $\mu$ ci/ml) as the active agent (see Table I), which encompasses claims 1-8.

Touitou fails to teach the dosage form of THC and an aerosol form of the composition.

Peart et al. teach a stable aerosol-dispensable pharmaceutical composition comprising a pharmaceutically effective concentration of delta-9-THC (Column 1, lines 20-27; claims), which is absorbed within seconds and delivered to the brain efficiently. Peart et al. also teach that an organic solvent such as ethanol can assist in solubilizing the delta-9-THC (Column 5, lines 50-52; claims). It is further taught that the optimal size of the respirable dose, or the mass of delta-9-THC in particles with aerodynamic diameters small enough to be delivered to and absorbed by the lungs, is less than 10  $\mu$ m in size (Column 6, lines 37-48), allowing for effective inhalation. A metered dose inhaler (MDI) is also taught for the aerosol administration of delta-9-THC.

Vachon et al. teach propylene glycol and water (in a ratio of 9:1) as a vehicle for holding THC (4.5 g/100ml) to be administered as an inhaled aerosol with a nebulizer (Materials, Methods and Subjects).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou and Peart and form a stable aerosolable composition with a pharmaceutically effective amount of delta-9-THC because Touitou teaches a composition comprised of ethanol, water, and propylene glycol with delta-9-THC as the active ingredient and Peart teaches an aerosolable

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composition with a pharmaceutically effective amount of THC. Further it would have been obvious to one skilled in the art at the time the invention was made to further combine the teachings of Vachon who teaches that a vehicle of propylene glycol and water in a ratio of 9:1 is capable of holding up to 4.5 g of THC/100 ml in clear solution, with Touitou and Peart, because both teach THC as a therapeutic agent and a solvent comprising ethanol.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the composition of Touitou in an aerosolable form of Peart et al. and Vachon et al., for more rapid onset of pharmacological action in the brain after administration of delta-9 THC. One having ordinary skill in the art at the time the invention was made would have been further motivated to employ the composition of Touitou in an aerosolable form of Peart et al. with delta-9 THC particles with aerodynamic diameters less than 10  $\mu\text{m}$  in size to allow for more effective inhalation and absorption by the lungs.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573) as applied to claims 1-8 above and further in view of LaMastro (U.S. Patent # 5,258,336).

Touitou, Peart et al., and Vachon et al. references are discussed above. Peart teaches administration of a composition via a metered dose inhaler (MDI) and Vachon teaches administration via a nebulizer.

Touitou, Peart et al., and Vachon et al. do not teach a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC with Type I Amber Glass.

LaMastro et al. teach a Type I amber glass composition that provides a high degree of chemical stability and protection from ultraviolet light for certain pharmaceutical compositions (Column 1, lines 10-13).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou, Peart, and Vachon in further view of LaMastro to house the composition in a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC in Type I amber glass. One having ordinary skill in the art at the time the invention was made would have been motivated to use Type I amber glass because it provides chemical stability and protection from ultraviolet light for pharmaceutical compositions.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29



USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 18-20 of U.S. Patent No. 6,747,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application and to U.S. Patent No. 6,747,058 are drawn to a composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising an alcohol, water and a glycol. The claims of the present application are further limited to claim more specifically that the alcohol is ethanol and the glycol is propylene glycol and the same ratios of ethanol, water and propylene glycol are listed in U.S. Patent No. 6,747,058. The present application also claims a sterile and/or



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preserved sealed unit-or multi-unit dosage form of delta-9-tetrahydrocannabinol comprising a container and a stable composition for rapid delivery by inhalation to the lungs and subsequently to the bloodstream wherein the said container comprises Type I Amber Glass, which is also claimed in U.S. Patent No. 6,747,058.

In view of the rejections to the pending claims set forth above, no claims are allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



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SUPERVISORY PATENT EXAMINER